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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,347	09/25/2001	J. Fernando Bazan	DX0903K1	9754

24265 7590 01/17/2008
SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
01/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/963,347	BAZAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Response to amendment

2. Claim 34 has been added as requested in the amendment filed on October 31, 2007. Following the amendment, claims 33 and 34 are pending and under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on October 31, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. (US Patent 6, 555, 520, April 29, 2003, filed May 9, 2001) for those reasons of record in section 6 of Paper mailed on August 28, 2007, in section 6 of Paper mailed on December 19, 2006 and earlier in 5 of Paper mailed on May 11, 2006, section 7 of Paper mailed on October 14, 2005, section 11 of Paper mailed on December 08, 2003 and in section 8 of Paper mailed on August 02, 2004.

Briefly, claims 33 and 34 are directed to isolated polypeptides encoded by a nucleic acid of SEQ ID NO: 1 ("IL-B50" polypeptides). Sims et al. document discloses polynucleotide sequences that have 100% identity to the instant SEQ ID NO: 1, thus fully anticipating the instant claim 33. Because the specific, substantial and credible utility of the instant IL-B50 polypeptides, which supports the enablement of IL-B50 polypeptides is only disclosed in the instant application, the effective filing date for the instant invention is determined as the filing date of the instant application (09/25/2001), which makes patent of Sims et al. a proper 102(e) reference.

Applicant traverses the rejection on the premises that the asserted stimulatory or inhibitory effect of the instant IL-B50 on hematopoietic cells is asserted in the '318 provisional application and thus, the instant application is entitled to the earlier filing date (p. 3 of the Response). Applicant further argues that the asserted effect is specific because "[n]ot all proteins can stimulate or inhibit hematopoietic cells" and substantial because it "provides a real world

benefit to the public due to the involvement of hematopoietic cells in immunotherapy and autoimmunity". "Moreover, the utility asserted in the '318 provisional application is credible [because it] was based on the inventors' recognition of the significant sequence and structural similarity between IL-7 and IL-50" (p. 4). Applicant's arguments have been carefully considered but are not persuasive for the following reasons.

As fully explained in the previous office actions of record, contrary to Applicant's statement, the similarity between the instant IL-B50 and IL-7 is significant only in terms of mathematical statistical analysis. The amino acid sequences of the instant IL-B50 encoded by SEQ ID NO: 1 and the known sequence of IL-7 are similar only by about quarter of the sequence length (28.1%), which means that 71.9% of the sequence of IL-B50 bears no resemblance to IL-7. The Examiner maintains that the instant specification fails to present any factual evidence or sound scientific reasoning to support a conclusion that molecules that have almost no common structure (28.1%) would have a common function and this function would be related to the effect on hematopoietic cells. There is no identification of a specific common structure that is known to be particularly associated with the function at the time of filing. All that is disclosed in the '318 application is a structure of IL-B50 polypeptide.

Applicant submits at p. 5 of the Response that "stimulatory or inhibitory effect of IL-B50 [could have been tested] using only routine experimentation" and refers to non-precedential opinion by the BPAI. As an initial matter, Applicant is reminded that Federal Circuit Rule 47.6(b) prohibits the citation of non-precedential opinions. Further, as fully explained in the previous office actions of record, it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility

of the claimed invention. The fact that Applicant submits that some experimentation may be required to practice the claimed invention simply confirms that the instant invention was not completed as filed, and, therefore, clearly lacks utility in currently available form.

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

In the instant case, characterization of the claimed polypeptide as having 28.1% structural similarity to the known polypeptide with diverse spectrum of functions and assertion that it would probably either inhibit or stimulate the activity of certain cell types (provisional application filed in 1998 states that "[i]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells") is clearly not sufficient to support the practical utility of the polypeptides as immediately available for public benefit.

With respect to citing post-filing publications to support the utility of the claimed invention (Applicant's Response at p. 5), Applicant is reminded that a later-published reference cannot be relied on for such a purpose:

> It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file.

Glass, 492 F.2d at 1232, 181 USPQ at 34. An "enabling disclosure" must include a utility that satisfies § 101. See *In re Fisher*, 421 F.3d 1365, 1378, 76 USPQ2d 1225, 1235 (Fed. Cir.

2005) ("It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101."); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) ("[S]urely Congress intended § 112 to pre-suppose full satisfaction of the requirements of § 101. Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention.").

Applicant is not citing Osborn et al. (top at p. 5 of the Response) "as evidence of the state of the art existing on the filing date of an application," *In re Hogan*, 559 F.2d at 605, 194 USPQ at 537, but for its disclosure of knowledge that became available to those skilled in the art only after the filing date of the instant application. Applicant seeks to rely on the later-published reference in order to bolster the evidence that SEQ ID NO:2 is likely to be useful in effects on hematopoietic cells. The Examiner is not aware of any case precedent held that post-filing evidence can be relied on with respect to any issue that is considered a question of fact rather than one of law. Such a rule would do nothing to encourage the full, enabling disclosure that is "[t]he sine qua non of a valid patent." *White Consolidated Inds., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791,218 USPQ 961, 963 (Fed. Cir. 1983).

> Rather, it would encourage applications based on speculation. In the biotech context, inventors would be rewarded for filing applications that disclose a protein and assert that it is useful for treating diseases, and listing every disease the inventor can think of. The inventor could then hope that evidence could be developed later to show that one of the guesses was right, and submit the later-arising data as evidence "confirming" the statement of utility in at least one respect.

The purpose of the patent system is to encourage innovation, not speculation. If an inventor cannot disclose at least one specific, substantial, and credible utility for a claimed invention, he is not ready to file a patent application. *Cf. Glass*, 492 F.2d at 1232, 181 USPQ at 34.

In the words of the Supreme Court, "what now seems without 'use' may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for it successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966).

7. Thus, because '492 application did not disclose how to use the instant claimed invention, the priority of the filing date of that application as well as to both provisional applications (60/131,298 and 60/101,318) was denied, see MPEP 201.11 (U.S.C. 120 states that the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112).

8. The instant application presented disclosure of new data obtained after the filing of the previous applications (see pp.64-69), which constitutes a CIP status of the instant application. With respect to the priority date, MPEP 706.02(a) makes it clear that "(B) If the application is a continuation-in-part of an earlier U.S. application or international application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.

As such, because the instant invention is only fully enabled in the instant specification, the effective filing date of the instant invention is awarded as the filing date of the instant application, 09/25/2001, which makes Sims et al. document a proper prior art under 102(e).

Conclusion

9. No claim is allowed.

10. This is a request for continued examination of applicant's earlier Application No. 09/963,347. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

January 14, 2008